DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 162 and 178

[T.D. 98–49]

RIN 1515–AB98

Prior Disclosure; Correction

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule; correction.

SUMMARY: Customs published in the **Federal Register** on May 28, 1998, a document revising the Customs Regulations regarding ''prior disclosure''. This document contains corrections to that document.

EFFECTIVE DATE: June 29, 1998.

FOR FURTHER INFORMATION CONTACT: Robert Pisani, Penalties Branch (202) 927–2344.

SUPPLEMENTARY INFORMATION:

Background

Customs published in the **Federal Register** (63 FR 29126) on May 28, 1998, a document revising the Customs Regulations regarding ''prior disclosure''. That document contained three technical errors which this document will correct.

Correction of Publication

Accordingly, the publication on May 28, 1998, of the final rule (T.D. 98–49) (63 FR 29126) (FR Doc. 98–14154) is corrected as follows:

1. On page 29132, in the first column, paragraph (a)(1) of § 162.74 is corrected to remove the word ''duties'' and insert in its place the words ''duties, taxes and fees''.

2. On page 29132, in the second column, paragraph (c) of § 162.74 is corrected by removing the words ''actual loss of duties'' in the heading and wherever it appears in the text and inserting in their place the words ''actual loss of duties, taxes and fees''. Also, paragraph (c) is corrected by removing the words ''actual duty loss'' or ''actual loss of duty'' and inserting in their place the words ''actual loss of duties, taxes or fees''.

3. On page 29132, in the third column, paragraph (f) of § 162.74 is corrected by inserting a comma after the word ''Fines'' the second time the word appears in the paragraph.

Dated: June 25, 1998

Joseph W. Clark,

Chief, Regulations Branch Harold M. Singer

[FR Doc. 98–17431 Filed 6–30–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0305]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-oxoundecyl as a pigment dispersant in all pigmented polymers intended for use in contact with food. This action is in response to a petition filed by Goldschmidt Chemical Corp.

DATES: The regulation is effective July 1, 1998; written objections and requests for a hearing by July 31, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 31, 1997 (62 FR 41053), FDA announced that a food additive petition (FAP 7B4550) had been filed by Goldschmidt Chemical Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the expanded safe use of siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-oxoundecyl as a pigment dispersant in all pigmented polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3725 should be amended as set forth below.

Information in the petition indicates that one of the constituents of the additive, i.e., hexadecene which is a starting material for the additive, leads to the formation in rabbits of a transient metabolite, 1,2-epoxyhexadecane (EHD). In a published study, EHD was reported to be a weak skin carcinogen in female Swiss mice (Ref. 1). FDA evaluated this study (Ref. 2) and has concluded that the evidence that EHD may be a weak dermal carcinogen in female Swiss mice does not preclude a conclusion that the petitioned use of the substance is safe[1].

First, the incidence of dermal tumors in EHD-treated mice was small (2 or 3 of 40 mice) and not statistically significant, assuming that control animals had no dermal tumors. Second, there were deficiencies in the conduct and reporting of this study. Third, dermal carcinogenicity is not highly predictive of carcinogenicity by other routes of exposure (Ref. 3). These observations support the agency's view that there is no evidence that suggests that EHD is likely to be a carcinogen when orally ingested, which is the route of exposure most directly relevant to the safety assessment of food additives.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under 21 CFR 25.31(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before July 31, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be

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[1] As noted, EHD is reported to be a weak skin carcinogen in female Swiss mice. This finding does not mean that EHD is a carcinogenic impurity of the additive.

If EHD were a carcinogenic impurity, FDA would evaluate such impurity under the general safety clause, using risk assessment procedures to determine whether there is a reasonable certainty of no harm that would result from the proposed use of the additive, *Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984).